



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2258]

Determination that TAGAMET (Cimetidine) Tablets and Other Drug Products were Not Withdrawn from Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Amy Hopkins, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6223, Silver Spring, MD 20993-0002, 301-796-5418, Amy.Hopkins@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and

dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicants, FDA withdrew approval of NDA 017920 for TAGAMET (cimetidine) Tablets in the Federal Register of June 8, 2011 (76 FR 33310), and NDA 018709 for CAPOZIDE (captopril and hydrochlorothiazide) Tablets in the Federal Register of March 19, 2012 (77 FR 16039).)

Application No.	Drug	Applicant
NDA 017920	TAGAMET (cimetidine) Tablet; Oral, 200 milligram (mg); 300 mg; 400 mg; 800 mg	GlaxoSmithKline, 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709
NDA 018155	OPTICROM (cromolyn sodium) Solution/Drops; Ophthalmic, 4%	Allergan Inc., 2525 Dupont Dr., Irvine, CA 92623
NDA 018709	CAPOZIDE (captopril and hydrochlorothiazide) Tablet; Oral, 25 mg/15 mg; 25 mg/25 mg; 50 mg/15 mg; 50 mg/25 mg	Apothecon Inc., P.O. Box 4500, Princeton, NJ 08543
NDA 018976	LEVATOL (penbutolol sulfate) Tablet; Oral, 10 mg; 20 mg	Auxilium Pharmaceuticals LLC, 640 Lee Rd., Chesterbrook, PA 19087
NDA 019958	CUTIVATE (fluticasone propionate) Cream; Topical, 0.05%	Fougera Pharmaceuticals Inc., 1 Health Plaza, Bldg. 434, East Hanover, NJ 07936
NDA 020713	MIRCETTE (desogestrel and ethinyl estradiol, and ethinyl estradiol) Tablet; Oral-28, 0.15 mg/0.02 mg; 0.01 mg	Teva Pharmaceutical Products Inc., 41 Moores Rd, P.O. Box 4011, Frazer, PA 19355
NDA 021410	AVANDAMET (metformin hydrochloride (HCl) and rosiglitazone maleate) Tablet; Oral, 500 mg/Equivalent to 1 mg Base	SmithKline Beecham Cork Ltd., Ireland, 2301 Renaissance Blvd., MC RN 0420, King of Prussia, PA 19406
NDA 021571	IQUIX (levofloxacin) Solution/Drops; Ophthalmic, 1.5%	Santen Inc., 555 Gateway Dr., Napa, CA 94558
NDA 021726	NIRAVAM (alprazolam) Orally Disintegrating Tablets; Oral, 0.25 mg; 0.5 mg; 1 mg; 2 mg	UCB Inc., 1950 Lake Park Dr., Smyrna, GA 30080
NDA 021768	FLUDEOXYGLUCLOSE F-18 Injectable; Intravenous 10-100 millicuries/milliliter	Weill Medical College Cornell University, 516 East 72nd St., New York, NY 10065
ANDA 076699	PARCOPA (carbidopa and levodopa) Orally Disintegrating Tablets; Oral, 10 mg/100 mg; 25 mg/100 mg; 25 mg/250 mg	UCB Inc., 1950 Lake Park Dr., Smyrna, GA 30080

Application No.	Drug	Applicant
ANDA 080248	ALBALON (naphazoline HCl) Solution/Drops; Ophthalmic, 0.1%	Allergan Inc., 2525 Dupont Dr., Irvine, CA 92623

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: January 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

BILLING CODE 4164-01-P

[FR Doc. 2015-00116 Filed 01/08/2015 at 8:45 am; Publication Date: 01/09/2015]